REMARKS

In response to the Office Action dated August 12, 2003, Applicants respectfully request reconsideration and withdrawal of the rejections of the claims.

Elected claims 1-9 and 19-24 were rejected under 35 U.S.C. §102, on the grounds that they were considered to be anticipated by one or more of the *Meador et al.*, *Bedington*, or *Antaki et al.* patents. It is respectfully submitted that these patents do not anticipate, nor otherwise suggest, the aspect of the invention to which the elected claims were directed. To further clarify the distinctions between the prior art and the invention, the original claims have been cancelled, and new claims 30-50 are being submitted herewith.

The elected claims are directed to a feature of the invention that is identified in the specification as the Back Off Response Mode. In this mode of operation, some of the functions that were performed by a human perfusionist assistant in an operating room are now carried out automatically. Typically, the assistant would set a fluid pump, such as a blood pump, to operate at a particular flow rate. The controller for the pump would then regulate its speed to maintain the flow rate at the desired level. If an alarm condition was presented, the assistant would manually reduce the indicated flow rate, to thereby cause the controller to reduce the pump speed, and thereby reduce pressure. If the alarm condition persisted, the perfusionist might continue to incrementally decrease the flow rate, until a satisfactory pressure was achieved.

The Back Off Response Mode of the present invention performs this type of operation automatically. Once a desired operating parameter has been established for the pump, for example manually by the perfusionist, the controller operates in the normal

fashion to regulate the pump speed so as to maintain the desired parameter. However, if an alarm condition is detected, the setpoint for the pump's operating parameter is automatically reduced, in the Back Off Response Mode. As a result of this reduced setpoint, the controller reduces the speed of the pump to maintain the new setpoint value for the operating parameter.

In essence, therefore, two levels of speed control are being carried out. The first, low level control, functions to maintain the speed of the pump at an established setpoint. The second level of control determines how the pump should behave clinically, to function in the manner of a perfusionist's assistant. Specifically, upon detecting an alarm condition, the second level of control adjusts the established setpoint to relieve the alarm condition.

It is respectfully submitted that none of the three applied patents discloses this type of operation. The Meador patent discloses a controller 308 for a blood pump 304 that functions to maintain the pump speed at a desired value, indicated by the signal 405. If the actual speed of the motor exceeds an allowable variance of this speed signal 405, the controller outputs an alarm signal. However, the Meador patent does not disclose that the desired speed for the pump motor is automatically reduced, for example by changing the speed signal 405. Rather, it appears that the perfusionist is expected to react to the alarm signal, and carry out any necessary adjustments of the pump's operating parameters. In other words, it is the perfusionist, rather than the pump controller, who establishes a new selected rotational speed for the pump motor.

The *Bedington* patent discloses a blood aspirator that controls the speed of a pump coupled to suction circuit, so as to maintain a predetermined concentration of bubbles in the

blood flow. Again, this patent discloses the first, low-level type of motor control, in which the speed of the motor is regulated to maintain a predetermined operating parameter. In this case, the operating parameter is the concentration of bubbles in the blood flow. However, the patent does not disclose a second, higher level type of control that is responsive to an alarm condition. Specifically, the patent does not disclose that, if an alarm condition occurs, the desired bubble concentration is changed, so as to reduce the pump speed, and thereafter operate the pump at a speed commensurate with this new level.

The *Antaki et al.* patent is concerned with operating a blood pump at its most effective level. As disclosed in column 1, lines 23-32, it is desirable to operate the pump close to the upper end of its acceptable speed range, i.e., just below the point at which negative pressure would result. To accomplish this objective, the patent discloses a technique in which the speed setpoint for the pump is continually increased until signs of imminent ventricular suction appear. At this point, the setpoint is slightly reduced.

Thus, in contrast to the claimed subject matter, the *Antaki et al.* patent does not disclose a perfusion system in which a setpoint is established for an operating parameter of the pump, and the speed of the pump is regulated to maintain operation at that setpoint. Nor does it disclose that, when an alarm condition is detected, the setpoint is automatically reduced, and the speed of the pump is then regulated to operate at this new setpoint value. Rather, in the system of the *Antaki et al.* patent, the setpoint is continuously being adjusted in an effort to maintain optimum efficiency. In other words, the controller of the *Antaki et al.* patent continuously "tests" the limit of safe operation, and adjusts the pump speed to operate just below that limit.

In view of the foregoing, therefore, it is respectfully submitted that the *Meador et al.*, *Bedington*, and *Antaki et al.* patents do not anticipate the Back Off Response Mode, as defined in claims 30-50. Reconsideration and withdrawal of the rejections are therefore respectfully requested.

Respectfully submitted,

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Date: December 12, 2003

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